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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/830,986	05/03/2001	Andreas Bernkop-Schnurch	030560-056	7285

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EXAMINER

RAMACHANDRAN, UMAMAHESWARI

ART UNIT	PAPER NUMBER
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1617

MAIL DATE	DELIVERY MODE
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05/03/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/830,986

Applicant(s)

BERNKOP-SCHNURCH,
ANDREAS

Examiner

Umamaheswari Ramachandran

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 28, 29, 31-33, 35-38 and 110 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 28, 29, 31-33, 35-38, 110 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Remarks

The examiner notes the receipt of the Arguments/Remarks and Rule 130, 131, 132 affidavits received in the office on 3/13/2007. Claims 1, 28, 29, 31-33, 35-38, 110 are pending in the application and are being examined on the merits herein.

Applicant's arguments, see p1, lines 20-24, p2, lines 1-5 filed 3/13/2007, and Rule 130, 131, 132 affidavit with respect to the rejection(s) of claim(s) 1, 28, 29, 31-33, 35-38, 110 under 35 U.S.C 102 rejection have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, new ground(s) of rejections are made.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 28, 29, 31-33, 35-38, 110 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for mucoadhesive polymers comprising the monomers acrylic acid, divinyl glycol, chitosan, sodium carboxymethylcellulose, sodium alginate, sodium hydroxypropylcellulose, hyaluronic acid, pectin, does not reasonably provide enablement for any other monomer. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. The specification does not provide sufficient information to support that

any other monomer other than the ones listed above would form a mucoadhesive polymer as claimed in claim 1.

The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApl's 1986) at 547 the court recited eight factors:

(1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

(1) The nature of the Invention:

All of the rejected claims are drawn to a mucoadhesive polymer comprising not more than 10 different monomers and at least one non-terminal thiol group said polymer exhibited a total work of adhesion (TWA) of more than 120 μ J to intestinal mucosa at a pH of 7 and said polymer being selected from the group consisting of a thiolated copolymer of acrylic acid and divinyl glycol, a thiolated polymer of chitosan, a thiolated polymer of sodium carboxymethylcellulose, a thiolated polymer of sodium alginate, a thiolated polymer of sodium hydroxypropylcellulose, a thiolated polymer of hyaluronic acid, a thiolated polymer of pectin, and derivatives of said thiolated polymers.

(2) Breadth of the claims:

The complex nature of the subject matter of this invention is greatly exacerbated by the breadth of the claims. The scope of the claims, which encompasses mucoadhesive polymer comprising not more than 10 different monomers, is broad.

(3) Guidance of the Specification:

The guidance given by the specification regarding mucoadhesive polymer is for the following polymers: thiolated copolymer of acrylic acid and divinyl glycol, a thiolated polymer of chitosan, a thiolated polymer of sodium carboxymethylcellulose, a thiolated polymer of sodium alginate, a thiolated polymer of sodium hydroxypropylcellulose, a thiolated polymer of hyaluronic acid, a thiolated polymer of pectin.

(4) Working Examples:

The specification provides description for the preparation of the thiolated polymers in general and in specific the preparation of thiolated copolymer of acrylic acid and divinyl glycol.

(5) The relative skill of those in the art:

The relative skill of those in the medical treatment art is high, requiring advanced education and training.

(6) The predictability of art:

Despite the advanced training in the medical treatment arts, the arts are highly unpredictable. It is well established that "the scope of enablement varies inversely with the degree of unpredictability of the factors involved," and physiological activity is generally considered to be an unpredictable factor. See *In re Fisher*, 427 F.2d 833, 839

(1970). The state of the art is such that it is not possible to predict the outcome of preparing a mucoadhesive polymer with any monomer (not more than 10 different monomers) in general.

(7) The Quantity of Experimentation Necessary:

In order to practice the above claimed invention, one of skill in the art would have to first envision formulation, dosage, duration, route and, in the case of human treatment, an appropriate animal model system for the claimed mucoadhesive polymer. One would then need to test every polymer whether they are mucoadhesive or not. If unsuccessful, one of skill in the art would have to envision a modification in the formulation, dosage, duration, route of administration etc. and appropriate animal model system, or envision an entirely new combination of the above and test the system again. In order to practice the applicant's invention, it would be necessary for one to conduct the preceding experimentation for every monomer. Therefore, it would require undue, unpredictable experimentation to practice the claimed invention of a mucoadhesive polymer comprising not more than 10 different monomers and at least one non-terminal thiol group. Genetech, 108 F.3d at 1366 states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

Therefore, a mucoadhesive polymer comprising not more than 10 different monomers and at least one non-terminal thiol group is not considered to be enabled by the instant specification.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 28, 29, 31-33, 35-38, 110 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 and claim 110 is directed to a mucoadhesive polymer comprising not more than 10 different monomers and said polymer being selected from thiolated polymers and derivatives of said thiolated polymers. The claims are indefinite with respect to the "derivatives of thiolated polymers".

Conclusion

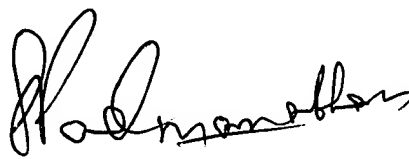
No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Umamaheswari Ramachandran whose telephone number is 571-272-9926. The examiner can normally be reached on M-F 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1617

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER